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10/659,413	09/10/2003	Peter Kite	0078140-000036	4621

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
08/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/659,413	KITE ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,34,39,41,42,45-47 and 56-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *32,34,39,41,42,45-47 and 56-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/21/2010,04/16/2010,02/02/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 02/02/2010, added new claims 61-64.

Applicant's amendment filed on 04/16/2010, amended independent claims 32, 56, 57.

Claims 32, 34, 39, 41-42, 45-47, and 56-64 are pending, and examined herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

35 USC § 103 Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 34, 39, 41, 42, 45, and 56-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656) above, in view of Wilder (US 6,500,861, PTO-892).

Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight EDTA or its sodium salts such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. See page 10, lines 10-25; and page 11, lines 6-10. It is also taught that the viscosity of the composition can be adjusted by adding sodium chloride. See page lines 15-16. The antimicrobial properties of the compositions

were also reported. It is further taught that by increasing the EDTA-Na4 concentration from 2 to 3.0 % by weight provided a substantial increase in bacteria reduction. See page 23, Table 8, prototype 10, wherein the composition comprises 3 % by weight of tetra sodium EDTA, NaCl, water and a pH of 9.5. The antimicrobial compositions comprising tetra-sodium EDTA taught by Fahim are used for topical application such as for cleaning skin. See page 41, claims 35-37. Regarding, the recitation wherein the solution further comprises 0.5 % to 10 % (V/V) ethanol, the antimicrobial compositions taught by Fahim comprise ethanol. See page 16, lines 3-6, Table 1, Table 2, table 8, wherein it is taught that 8 weight percent of sulfotex, sodium lauryl ether sulfate employed in the compositions therein contains about 13-16 % of ethanol i.e less than 10 % (v/v) of ethanol is present in the compositions therein.

Fahim does not expressly teach that the composition is packaged in a sterile, pyrogen free form.

Wider teaches antimicrobial compositions for eliminating infections from various surfaces and materials, including the surface of the body. It is also taught that the antimicrobial compositions can be administered as a liquid either orally or through a suitable delivery system, such as a catheter. See column 1, lines 8-20; column 2, lines 30-34; and column 4, lines 10-14. It is further taught that the antimicrobial compositions are packaged in a sterile and pyrogen free form, and can be introduced into the abdominal cavity through a catheter. See column 6, lines 9-10; column 7, lines 51-55.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form.

One of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as conventional with antimicrobial compositions with the expectation of using the composition in catheters.

While the references does not explicitly state that "composition has an osmolarity of from 240-500 mOsM/Kg", as in claim 55, since Fahim discloses the same sodium salts of EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Fahim discloses the same tetrasodium EDTA as that recited in the instant invention, the composition should possess claimed properties.

While the references does not explicitly state that "the EDTA salt provides at least 50 % of a total antimicrobial activity of the composition" as in claims 58-60, since Fahim discloses the same sodium salts of EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Fahim discloses the same salts of EDTA as that recited in the instant invention, the composition should possess claimed properties.

In claims 56, 62 the intended use of a product or composition "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes", do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656), in view of Wider (US 6,500,861 B1), as applied to Claims 32, 34, 39, 41, 42, 45, and 56-60 above, and further in view of Root et al. (Antimicrobial Agents and Chemotherapy. Nov. 1988, pages 1627-1631, PTO-892).

Fahim, and Wider are as discussed above.

Fahim does not specifically teach the antimicrobial composition in a single-dosage vial.

Root et al. teaches a method for disinfecting a catheter by contacting (flushing) with an antimicrobial composition of aqueous EDTA solution having a concentration of 20 mg/ml. The EDTA used by Root et al. is in the form of the disodium salt. Root also teaches that the EDTA is used as a topical antiseptic in gram-negative infections. See page 1627, paragraphs 3, and 6. Root further teaches a sterile polystyrene test tubes (vials) containing the antimicrobial composition of disodium EDTA at a concentration of 20 mg/ml (2 %). See page 1628, lines 18-21.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile condition in a single-dosage vial from the teachings of Root et al.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656, PTO-892), in view of Wilder (US 6,500,861, PTO-892), as applied to 32, 34, 39, 41, 42, 45, and 56-60 above, and further in view Remington's Pharmaceutical Sciences.

Fahim fails to recite the employment of the composition in a prefilled syringe.

Remington's Pharmaceutical Sciences teaches sterile, pyrogen free solutions of sodium chloride as ideal for injection. It also discloses that hypodermic syringes are used for injection of liquids. See page 1837. Remington also warns against injection of solutions containing pyrogens (See page 835, column 2, paragraph 1), and to maintain conventional sterile methodology for injected medicaments.

Possessing this teaching by Remington Pharmaceutical Sciences the skilled artisan would have been motivated to provide a syringe filled with an EDTA solution with the expectation of using such sterile, pyrogen free solution for injection.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive.

Applicant argues that "the "ethanol" referred to by Fahim is actually the repeating unit (shown below) in the middle of the chain of the SLES: -(CH2CH2O)n". These

arguments have been considered, but not found persuasive. The repeating unit in sodium lauryl ether sulfate (SLES) is usually referred as ethylene oxide and not ethanol. For example, see page 12, lines 3-7, where Fahim teaches that sodium lauryl ether sulfate employed in the composition therein Sulfotex contains 3ETO i.e 3 ethylene oxide units or 3 moles of ethoxylation and not ethanol (ETOH). The 13-16 % ethanol that Fahim is referring to on page 16, lines 5 is the ethanol present in the Sulfotex 6040 composition employed in the antimicrobial compositions therein.

Applicant's arguments, and the Declaration provide by Olmstead & Ketteridge regarding toxicity have been considered, but not found persuasive as discussed below.

Applicant argues that "since the handwash of Fahim is toxic, the handwash is not actually useful on the skin of a user" These arguments have been considered, but not found persuasive because contrary to applicant's arguments that "the handwash of Fahim is toxic, the handwash is not actually useful on the skin of a user", Fahim teaches that the composition therein are useful in cleaning skin, and the compositions are safe. See page 5, wherein it is taught that the composition therein is mild and does not irritate skin. Further, Fahim on page 28, lines 29-31, recites that the compositions therein are not toxic, did not have any adverse pharmacologic effects when the animal were exposed to the compositions therein.

Applicant argues that "use of the handwash of Fahim would involve exposure to glutaraldehyde which causes the following health effects: throat or lung irritation; asthma and difficulty breathing; contact and/or allergic dermatitis; nasal irritation; sneezing; wheezing; burning eyes and conjunctivitis. Declaration of Olmstead &

Ketteridqe, paragraph 8." These arguments have been considered, but not found persuasive. As discussed above Fahim teaches that the compositions therein are not toxic, did not have any adverse pharmacologic effects when the animals were exposed to the compositions therein.

Applicant argues that "The handwash of Fahim also contains 4-chloro-3,5-dimethyl phenol (Chloroxylenol, also known as parachlorometaxylenol, or PCMX) as a component. While PCMX is used as an antimicrobial in soaps, shampoos, and sprays, it has never been approved for oral or parenteral administration. Declaration of Olmstead & Ketteridge, paragraph 5. " These arguments have been considered, but not found persuasive. The arguments are not commensurate in scope with instant claims because instant claims do not recite administration of instant compositions orally or parenterally. Further, as discussed above Fahim teaches that the compositions therein are not toxic, did not have any adverse pharmacologic effects when the animals were exposed to the compositions therein.

Further, regarding applicant's arguments regarding triclosan, it is pointed out that triclosan is a well known antibacterial agent used in variety of products including for example, toothpaste.

Applicant argues that "Clearly, due to the toxicity of the handwash of Fahim, one skilled in the art would not employ the Fahim compositions in catheters. Because one skilled in the art would not employ the Fahim compositions in catheters, one skilled in the art would have no reason to modify the handwash to be in a sterile pyrogen free form with the expectation of using the Fahim composition in catheters." These

arguments have been considered, but not found persuasive as discussed above, Fahim teaches that the skin care treatments compositions therein are safe and not toxic and biocompatable. It is pointed out that the intended use of a product or composition "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes", do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant argues that the "the handwash of Fahim cannot be sterilized by the method of Wider, heat. Declaration of Olmstead & Ketteridge, paragraph 14. Triclosan is heat stable only up to 482°-F (250°-C), but it readily decomposes into dioxins." These arguments have been considered, but not found persuasive. It is pointed out that Wilder's reference was employed for its teachings that antimicrobial compositions are packaged in a sterile and pyrogen free form, and not for a method of sterilizing the antimicrobial composition.

Applicant argues that "even if sterile, pyrogen-free, deionized water (as used in Wider) were used with the Fahim composition, the final product would be very difficult to render pyrogen free since none of the other ingredients are ready available with a specification of low or no pyrogens. Declaration of Olmstead & Ketteridqe, paragraph 15. Pyrogens are very difficult and expensive to remove from a final formulation, and the acceptable production method to assure no pyrogens in a final formulation is to only

utilize ingredients containing no pyrogens." These arguments have been considered, but not found persuasive. The arguments are not commensurate in scope with instant claims which are drawn to composition and not method of making the composition.

Fahim teaches antimicrobial compositions comprising tetrasodium EDTA. Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form. Accordingly, it would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form. One of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as conventional with antimicrobial compositions with the expectation of using the composition in catheters. "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1731 (2007). In the present case, one of ordinary skill in the art aware of the use of antimicrobials in pyrogen free form as in Wider, would have been motivated to use other antimicrobials, such as EDTA, in pyrogen free form.

Claims 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Root et al. (Antimicrobial Agents and Chemotherapy. Nov. 1988, pages 1627-1631,

PTO-892), in view of Raad et al. (US 6,267,979, PTO1449), and further in view of Wilder (US 6,500,861, PTO-892).

Root et al. teaches a method for disinfecting a catheter by contacting (flushing) with an antimicrobial composition of aqueous EDTA solution having a concentration of 20 mg/ml. The EDTA used by Root et al. is in the form of the disodium salt. Root also teaches that the EDTA is used as a topical antiseptic in gram-negative infections. See page 1627, paragraphs 3, and 6. Root further teaches a sterile polystyrene test tubes (vials) containing the antimicrobial composition of disodium EDTA at a concentration of 20 mg/ml (2 %). See page 1628, lines 18-21.

The EDTA used by Root et al is in the form of the disodium salt. Raad et al., however, teaches that it is known in the art that both disodium and tetrasodium EDTA salts have "a significant growth inhibitory effect against species of funagal and bacterial microorganisms including Aspergillus, Fusarium, Candida, Psuedomonas, vancomycin-resistant enterococci, and multidrug resistant Stenotrophomonas". See col.8, lines 26-33; col.9, line 13 to col. 10, line 4; Table 1; and Figures 1-4; column 26, claim 51. It would have been obvious to one of ordinary skill in the art to substitute the tetrasodium salt of EDTA for the disodium salt employed by Root et al, as both salts are disclosed to be suitable for use in methods of microbial biofilm disruption. As Root et al discloses using a concentration of 20 mg/ml, the combination with Raad et al. will necessarily have an intrinsic "bactericidal effect over a broad spectrum of microbes and a destructive effect against a variety of yeasts."

Root et al. does not expressly teach that the composition is packaged in a pyrogen free form.

Wider teaches antimicrobial compositions for eliminating infections from various surfaces and materials. It is also taught that the antimicrobial compositions can be administered as a liquid either orally or through a suitable delivery system, such as a catheter. See column 1, lines 8-20; column 2, lines 30-34; and column 4, lines 10-14. It is further taught that the antimicrobial compositions are packaged in a sterile and pyrogen free form, and can be introduced into the abdominal cavity through a catheter. See column 6, lines 9-10; column 7, lines 51-55.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition containing tetrasodium EDTA in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form.

One of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as conventional with antimicrobial compositions with the expectation of using the composition in catheters.

While the references does not explicitly state that “the antiseptic composition has a pH of at least 9.5”, and the composition has an osmolarity of from 240-500 mOsM/Kg”, as in claim 64, it is pointed out that as the combined teachings renders the claimed composition obvious, the property of such a claimed composition will also be

rendered obvious by the prior art teachings, since the properties, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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